

Section 5
PowerHickman Central Venous Catheter
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a)

AUG - 9 2006

5.1 General Information

Submitter Name: Bard Access Systems, Inc. (BAS)
[Wholly owned Subsidiary of C. R. Bard, Inc.]
Address: 5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116
Telephone Number: (801) 595-0700 ext. 5541
Fax Number: (801) 595-5425
Contact Person: Michaela Rivkovich
Date of Preparation: June 30, 2006
Registration Number: 1720496
Additional Registration Numbers:
C. R. Bard: 2212754

5.2 Subject Device Information

Device Name: PowerHickman™ Central Venous Catheter
Trade Name: PowerHickman™
Common/Usual Name: Central Venous Catheter
Classification Name: Long Term Intravascular Catheter
21 CFR 880.5970, Class II
80 LJS – Long Term Intravascular Catheter
Classification Panel: General Hospital

5.3 Predicate Device Information

Device Name: PowerLine™ Central Venous Catheter
Trade Name: PowerLine™
Common/Usual Name: Central Venous Catheter
Classification Name: Long Term Intravascular Catheter
21 CFR 880.5970, Class II
80 LJS – Long Term Intravascular Catheter
Classification Panel: General Hospital
510(k) Clearance: K050185, concurrence date May 26, 2005
K051417, concurrence date June 30, 2005
K051991, concurrence date October 20, 2005

5.4 Intended Use

The PowerHickman™ catheter is intended for short or long term access to the central venous system for intravenous therapy and blood sampling.

5.5 Indications for Use

The PowerHickman™ catheter is indicated for short or long term access to the central venous system. The PowerHickman™ catheter is designed for the administration of I.V. fluids, blood products, drugs, parenteral nutrition solutions, as well as blood withdrawal, power injection of

contrast media and allows for central venous pressure monitoring. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

5.6 Device Description

The PowerHickman™ catheters are open-ended, long-term central venous catheters. The catheters are made of polyurethane material to which a purple colorant has been added. Purple colorants were added to the catheter materials to provide the catheter with an appearance that allows the end user to differentiate Bard's power injectable catheters from other manufacturers' power injectable catheters. The PowerHickman™ catheters are available in 8 Fr single lumen and 9.5 Fr dual lumen catheter configurations. The catheters are packaged in intermediate and microintroducer kits that incorporate kit components designed to meet the needs of the respective placer.

5.7 Technological Comparison to Predicate Device

The technological characteristics of the PowerHickman™ catheters are substantially equivalent to those of the predicate PowerLine™ catheters in terms of intended use, application, user population, basic design, performance and labeling.

5.8 510(k) Substantial Equivalence Decision Tree

New device is compared to Marketed Device?

Yes.

Does the new device have the same indication statement and intended use as the predicate?

Yes. The intended use and indications for use are a combination of the indications from the predicate PowerLine catheters 510(k) K050185, K051417 and K051991.

Does the new device have the same technological characteristics, e.g. design, materials, etc.?

Not in all regards. The principles of operation and basic design are the same as the predicate PowerLine catheter. The main differences are new catheter sizes and the use of ChronoFlex polyurethane material for catheter shaft and junction/bifurcation.

Could the new characteristics affect safety or effectiveness?

Yes. The design changes may affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety or effectiveness questions?

No. Safety and effectiveness questions are the same as for the predicate devices.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. Testing was performed to assess the new characteristics and was based on the following applicable standards and FDA guidance document:

- ❖ *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*
- ❖ *BS/EN/ISO 10555-1: 1997, Sterile, single-use intravascular catheters, Part 1. General requirements*
- ❖ *ISO 10555-1: 1995, Sterile, single-use intravascular catheters, Part 1. General requirements, Amendment 1: 1999*
- ❖ *BS/EN/ISO 10555-3: 1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters*

PowerHickman™ Catheter
Traditional 510(k)

- ❖ *ISO 594-2: 1998, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings*
- ❖ *ASTM F640-79 (reapproved 2000), Standard Test Methods for Radiopacity of Plastics for Medical Use*
- ❖ *AAMI/ANSI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- ❖ *AAMI/ANSI/ISO 10993-1:2003, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile*
- ❖ *IEC 60601-2-34: 2000-10, Medical electrical equipment – Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment*
- ❖ *AAMI TIR9: 1992, Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring*
- ❖ *ANSI/AAMI BP22: 1994, Blood Pressure Transducers*

Are performance data available to assess effects of new characteristics?

Yes. Bench testing was based on the above referenced guidance document and standards.

Performance data demonstrate equivalence?

Yes. The PowerHickman™ Central Venous Catheters met performance criteria of the safety and effectiveness tests performed and, based on FDA's decision tree, are substantially equivalent to the predicate PowerLine™ Central Venous Catheters, K050185, concurrence date May 26, 2005, K051417, concurrence date June 30, 2005, and K051991, concurrence date October 20, 2005



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2006

C.R. Bard, Incorporated
Ms. Michaela Rivkovich
Senior Regulatory Affairs Specialist
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K061179

Trade/Device Name: 8 Fr Single Lumen and 9.5 Fr Dual Lumen PowerHickman™
Central Venous Catheters

Regulation Number: 880.5970

Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter

Regulatory Class: II

Product Code: LJS

Dated: June 30, 2006

Received: July 3, 2006

Dear Mr. Rivkovich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

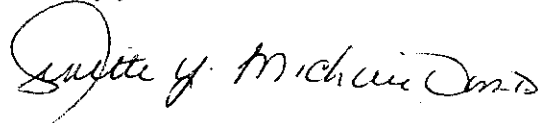
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Section 4
Indications for Use

510(k) Number (if known): K061179

Device Name: 8 Fr Single Lumen and 9.5 Fr Dual Lumen PowerHickman™ Central Venous Catheters

Indications for Use:

The **PowerHickman** catheter is indicated for short or long term access to the central venous system. The **PowerHickman** catheter is designed for the administration of I.V. fluids, blood products, drugs, parenteral nutrition solutions, as well as blood withdrawal, power injection of contrast media and allows for central venous pressure monitoring. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. [Signature]

(in Sign-Off)
Division of Anesthesiology, General Hospital,
Quality Control, Dental Devices

510(k) Number: K061179

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